

**510 (k) SUMMARY
FOR
OLYMPUS OTIS URETHROTOME SYSTEM**

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K950719
DEC 11 1996

Device Name: Olympus Otis Urethrotome System

Common/Usual Name: Endoscopic Accessories for Urology

Classification Name: Endoscope and Accessories

Predicate Devices: Olympus Urology System (K790071)
Olympus Infant Resectoscope and Accessories (K904940)
Olympus Flexible & Rigid Urethrotome System (K904339)

Karl Storz Endoscopes & Accessories for Urology
(Unknown).

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Summary Preparation Date: October 1, 1996 (Revised)

Statement of Intended Use:

Otis Urethrotome for Adult Use

Olympus O0216 Otis Urethrotome and O2160 Replacement Blade are intended to be used for endoscopic and treatment within the urethra in adults. When compared with the intended use of predicate devices, the intended use of the subject devices has not been changed.

Otis Urethrotome for Pediatric Use

Olympus O2161 Otis Urethrotome and O2162 Replacement Blade are intended to be used for endoscopic treatment within the urethra in children. When compared with the predicate devices, the Olympus subject devices are intended for pediatric use, while the Olympus predicate devices were cleared for Infant Use in 510(k) # K904940.

Device Description

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Olympus America Inc. has been marketing rigid endoscopes, hand instruments, associated accessories, and ancillary equipment for Urological Endoscopy since 1979. The Olympus Urethrotomy System includes the following products.

1. Otis Urethrotome for Adult Use
 - O0216 Otis Urethrotome, 16 cm
 - O2160 Replacement Blade for O0216 Urethrotome
2. Otis Urethrotome for Pediatric Use
 - O2161 Otis Urethrotome, 10.5 cm
 - O2162 Replacement Blade for O2162 Urethrotome

When these subject devices are compared with the predicate devices, which were cleared in 510(k)s # K790071 and K904940, no significant changes or modifications in intended use, design, material, function, method of operation, or reprocessing that could affect the safety and efficacy of the devices have occurred.

General Safety

When compared with the predicate devices, Olympus Otis Urethrotome System does not incorporate any significant change in intended use, method of operation, material, or design that could affect the safety or effectiveness of the subject device.